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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,715	08/16/2006	Abelardo Silva	66781-006USNATL	3064
61263 7590 07/21/2009 PROSKAUER ROSE LLP 1001 PENNSYLVANIA AVE, N.W., SUITE 400 SOUTH WASHINGTON, DC 20004				
EXAMINER				
TELLER, ROY R				
ART UNIT		PAPER NUMBER		
1654				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,715

Applicant(s)

SILVA ET AL.

Examiner

ROY TELLER

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28, 30, 48, 53, 81 and 136-145 is/are pending in the application.
- 4a) Of the above claim(s) 48, 53, 81 and 136-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-28, 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of the restriction requirement in the reply filed on 6/19/09 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner to search the claimed inventions together. This is not found persuasive because the inventions have acquired a separate status in the art due to their recognized divergent subject matter. See, restriction requirement, page 4.

The requirement is still deemed proper and is therefore made FINAL.

Claims 48, 53, 81 and 136-145 are withdrawn as being drawn to non-elected subject matter.

Claims 18-28 and 30 are under examination as they read on the elected species of Formula I: AV is WMEWDREINNYTSLIHSLIEESQNQKEKNEQELL, Pr is human serum albumin (HSA).

Claim Objections

Claim 24 is objected to for failing to include SEQ ID NO's for the instant peptides.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 19, 23, 24, 25, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 9, and 10 of copending Application No.10/ 478,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a complex of formula I: wherein Av is AV is WMEWDREINNYTSLIHSLIEESQNQKEKNEQELL, linkers, and Pr is human serum albumin (HSA), wherein the complex possesses antiviral activity. The '811 application discloses a compound of formula I-VIII that includes the WMEWDREINNYTSLIHSLIEESQNQKEKNEQELL peptide, linker, and albumin that inhibit viral activity (HIV, HPV or MeV).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-28 and 30 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a composition and a method for inhibiting the activity of HIV, does not reasonably provide enablement for a composition and a method for inhibiting antiviral activity in vivo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

Nature of the invention. The claims are drawn to a composition comprising a formula of claim 1 wherein the complex possesses antiviral activity in vivo.

State of the prior art. At the time the invention was made, C34 peptides (a 34-residue peptide corresponding to the C-terminal heptad repeat of gp41 of HIV-1 Env; WMEWDREINNYTSLIHSLIEESQNQQEKNEQELL) had been shown to inhibit fusion between HIV-1 and cells. SIV and HIV-2 C34 peptides derived from their respective C-terminal heptad repeats of gp41 had also been shown to inhibit SIV and HIV-2 envelope-mediated fusion. In addition, synthetic C34 peptides from SIV (WQEWERKVDLFLEENITALLEEAIQQEKNMYELQ) had been shown to inhibit HIV-1 infections (see Malashkevich et al.).

Breadth of the claims. The claims are very broad, encompassing a complex that possesses antiviral activity in vivo.

Working examples. One working example is provided in the specification showing the activity of the complex of claim 1 against HIV. No working examples are disclosed in the

specification showing the effectiveness of the complex of claim 1 for inhibiting any other viral activity in vivo.

Guidance in the specification. The specification provides little guidance regarding practice of the claimed complex. The specification refers to the use of C34 peptides to inactivate gp41, and thus, prevent or reduce HIV-1 entry into cells (See background) and refers to the synthesis of the modified or conjugated C34 peptides. In addition, there is one example showing the effect of the claimed compounds on HIV-1 activity. The specification does not disclose the effect, if any, the claimed complex has on any other virus.

Predictability of the art. In the instant application, Applicants have not disclosed or shown the effectiveness of the claimed C34 derivatives against viruses other than HIV, citing only that “the viruses that may be inhibited by the peptides include, but are not limited to, all strains of viruses listed, e.g., in US 6,013,263 and US 6,017,536 at Tables V-VII and IX-XIV therein.” This extensive list of viruses contains many classes of virus that are completely unrelated to HIV in structure, morphology and mode of infection.

The C34 derivatives of the art are derived from gp41 of HIV-1, HIV-2 or SIV. gp41 has a specific sequence and structure, and the C34 peptides derived from gp41 fold into a specific structure (a coiled coil structure) that interacts with another coiled coil structure of gp41 (see Figures 1 and 4 of Malashkevich et al.). Based on the teachings of the prior art and the structure of C34, it does not appear that the C34 peptides derived from HIV will interact with viruses other than HIV.

Amount of experimentation. It is not known whether the claimed complex have any effect against viruses other than HIV. Applicants have identified compounds, which might be effective against some viruses (e.g., HIV-1 and HIV-2), but essentially all of the work required to ultimately develop a composition and treatment method for viruses other than HIV has been left for others.

Given the breadth of the claims, the lack of guidance in the specification, and the predictability of the art, it would require undue experimentation for one skilled in the art to use the claimed composition and method.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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1654
7/16/09

/Christopher R. Tate/
Primary Examiner, Art Unit 1655